

PATIENT INFORMATION LEAFLET

Telmisartan and Amlodipine Tablets IP
(80 mg + 5 mg)

TELSARTAN AM 80

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What TELSARTAN AM 80 is and what it is used for
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1. What TELSARTAN AM 80 is and what it is used for

TELSARTAN AM 80 tablet is a prescription medicine that contains telmisartan and amlodipine.

TELSARTAN AM 80 tablets may be used to treat high blood pressure (hypertension):

- ❖ when one of these medicines (or a similar one) is not enough to lower your high blood pressure
- ❖ as the first medicine to lower your high blood pressure if your doctor decides you are likely to need more than one medicine

2. What you need to know before you take TELSARTAN AM 80

Do not take TELSARTAN AM 80

You should not take telmisartan and amlodipine tablets if you are allergic (hypersensitive) to the active ingredients (telmisartan or amlodipine) or any of the other ingredients listed at the end of this leaflet.

For patients with diabetes, if you are taking telmisartan and amlodipine tablets you should not take aliskiren.

Warnings and precautions

Before you take telmisartan and amlodipine tablets, tell your doctor if you:

- ❖ are pregnant or are planning to become pregnant.

- ❖ are breastfeeding or plan to breastfeed. Telmisartan and amlodipine tablets can pass into your breast milk and may harm your baby.

You and your doctor should decide if you will take telmisartan and amlodipine tablets or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take TELSARTAN AM 80 tablets.

- ❖ have liver problems
- ❖ have kidney problems
- ❖ have heart problems
- ❖ have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.

For patients with diabetes, if you are taking telmisartan and amlodipine tablets you should not take aliskiren.

TELSARTAN AM 80 tablets may affect the way other medicines work, and other medicines may affect how telmisartan and amlodipine tablets work. Especially tell your doctor if you take:

- ❖ Aliskiren
- ❖ digoxin (Lanoxin®)
- ❖ lithium (Lithobid®, lithium carbonate, lithium citrate)
- ❖ aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- ❖ other medicines that may be used to treat high blood pressure or a heart problem
- ❖ simvastatin (Zocor®, Vytorin®)
- ❖ water pills (diuretics)

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

If any of the above applies to you, tell your doctor or pharmacist before you take TELSARTAN AM 80.

3. How to take TELSARTAN AM 80

Take TELSARTAN AM 80 tablets exactly as your doctor tells you to take it.

Your doctor will tell you how much telmisartan and amlodipine tablets to take and when to take it. Your doctor may change your dose if needed.

Take TELSARTAN AM 80 tablets one time each day at the same time. Take TELSARTAN AM 80 tablets with or without food.

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Take the next dose at your regular time.

If you take too much TELSARTAN AM 80 tablets, call your doctor or go to the nearest hospital emergency room right away.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

4. Possible side effects

TELSARTAN AM 80 tablets may cause serious side effects, including:

Injury or death to your unborn baby.

Low blood pressure (hypotension) is most likely to happen if you also:

- ❖ take water pills (diuretics)
- ❖ are on a low-salt diet
- ❖ get dialysis treatments
- ❖ have heart problems
- ❖ get sick with vomiting or diarrhea

If you feel faint or dizzy, lie down and call your doctor right away.

Kidney problems: Kidney problems may get worse if you already have kidney disease. You may have changes in your kidney test results, and you may need a lower dose of telmisartan and amlodipine tablets. Call your doctor if you get:

- ❖ swelling in your feet, ankles, or hands
- ❖ unexplained weight gain

Call your doctor right away if you get any of the symptoms listed above.

Heart problems or heart attack: Heart problems may get worse in people who already have heart disease. This may happen when you start telmisartan and amlodipine tablets or when there is an increase in your dose of telmisartan and amlodipine tablets. Get emergency help if you get worse chest pain or chest pain that does not go away.

High potassium in the blood (hyperkalemia): Your doctor may check your potassium levels as needed.

- ❖ Muscle rigidity, tremor and/or abnormal muscle movement.

Rare, serious allergic reactions may happen. Tell your doctor right away if you get any of these symptoms:

- ❖ swelling of face, tongue, throat
- ❖ difficulty breathing
- ❖ skin rash

The most common side effects of telmisartan and amlodipine tablets include:

- ❖ swelling in your hands, ankles, or feet
- ❖ feeling like your heart is pounding or racing
- ❖ flushing or sudden redness of the face and neck
- ❖ dizziness
- ❖ back pain
- ❖ feeling tired or sleepy
- ❖ abdominal pain, nausea, or diarrhea
- ❖ low blood pressure or a sudden drop in blood pressure with fainting

These are not all the possible side effects of telmisartan and amlodipine tablets. Tell your doctor if you have any side effect that bothers you or that does not go away.

5. How to store TELSARTAN AM 80

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Store in a dry place at or below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TELSARTAN AM 80 contains

The active substances are Telmisartan and Amlodipine.

TELSARTAN AM 80

Each uncoated bilayered tablet contains:

Telmisartan IP 80 mg

Amlodipine Besylate IP equivalent to Amlodipine 5mg

Colour: Iron Oxide Yellow

What TELSARTAN AM 80 looks like and contents of the pack

TELSARTAN AM 80 tablets are White/Yellow, Oblong, biconvex, uncoated bilayered tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.



Manufactured by :
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